

REMARKS

Sequence Requirements

The Office cites the present application as failing to comply with the requirements of 37 CFR 1.821 - 1.825. The Office specifically cites sequences on pages 44 and 56 of the Specification.

In response, the applicants provide herewith a substitute computer readable form (CRF) and a substitute paper copy of the Sequence Listing for the present application. The present Sequence Listing contains all 10 (ten) sequence disclosures of the application encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), whereas the previous sequence listing filed by the applicants on May 27, 2003, inadvertently contained only 4 (four) of said sequence disclosures.

As all sequence disclosures of the application encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) have been submitted to the Office per sequence rule requirements of 37 CFR 1.821-1.825, it is respectfully believed by the applicants that the present application is in compliance with the sequence rule requirements of 37 CFR 1.821-1.825.

**Statement regarding content of the paper and computer readable copies of the
Sequence Listing provided herewith**

The applicants hereby respectfully state that the content of the paper copy of the Sequence Listing provided herewith is the same as the computer readable form (CRF) copy of the Sequence Listing provided herewith, and said copies include no new matter.

New Matter

The applicants' amendment filed on April 22, 2004 stands objected to in the Office action under 35 USC 132 as introducing new matter. The Office cites the added material which is not supported by the original disclosure as being the phrase "selectively amplify a first and second molecular marker for breast cancer" in lines 4-5 of claim 16.

In response, independent claim 16 is amended herein. As amended, the present claim 16 does not contain the phrase "selectively amplify a first and second molecular marker for breast cancer". It is therefore believed by the applicants that the new matter objection has been overcome.

Claim Rejections Under 35 USC §112, First Paragraph

Claims 16-20 and 88 stand rejected in the Office action under 35 USC 112, first paragraph as failing to comply with the written description requirement and as containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventor(s), at the time the application was filed, had possession of the claim invention. The rejection is respectfully traversed.

At Page 3 of the Final Office action, second paragraph, the Office specifically cites the phrase “selectively amplify a first and second molecular marker for breast cancer” in lines 4-5 of claim 16 as failing to comply with the written description requirement.

As noted in the above section entitled “New Matter”, the applicants have amended independent claim 16 (dependent claims 19 and 20 have also been amended and dependent claim 88 has been canceled). None of the pending claims contain the phrase “selectively amplify a first and second molecular marker for breast cancer.

At Page 3 of the Final Office action, third paragraph, the Office references the reasons of record advanced in the previous Office action mailed 10/20/2003. It is the applicants’ understanding that the reasons of record of the previous Office action are directed to the

applicants' earlier use of the language "primer set comprising SEQ ID NO: 1" (emphasis added). Page 4, lines 6-8 of the Office action mailed 10/20/2003, state "No other sequences which "comprises, or comprising" SEQ ID NO: 1 and 2 were disclosed. The specification does not set for the metes and bounds of that comprises or comprising SEQ ID NO: 1 or 2..."

The applicants respectfully note that the language "primer set comprising SEQ ID NO: 1" is not present in the pending claims. The claimed invention is directed to methods of screening a patient for breast cancer comprising "assaying for the presence of human papillomavirus in a sample from a biopsy taken from a patient, wherein said assaying comprises amplifying human papillomavirus gene sequences by use of a pair of primers to produce an amplified product, and probing said amplified product for the presence of HPV 16 and a second human papillomavirus selected from the group consisting of HPV18, HPV31, HPV 33, HPV35, HPV45, HPV58, wherein said pair of primers is SEQ ID NO: 1 and SEQ ID NO: 2, and wherein presence of HPV 16 and said second human papillomavirus is indicative of breast cancer in said patient."

The applicants respectfully direct attention to Example 1, beginning at page 42 of the originally filed Specification, and originally filed Figures 1-6 which provide support, enablement and written description of the claimed invention.

In view of the above amendments and remarks, it is believed by the applicants that the rejection of claims 16-20 under 35 USC 112, First Paragraph have been overcome.

Claim Rejections Under 35 USC §112, Second Paragraph

Claims 16-20 and 88 stand rejected in the Office action under 35 USC 112, second paragraph, as being vague and indefinite.

Specifically the Office cites claim 16 as vague and indefinite and cites use of the language “designed to selectively amplify” as confusing and “molecular marker” as vague and indefinite. Claim 16 also stands objected to in the Office action for a typographical error in line 7, wherein “..” has been inserted after “SEQ ID NO: 1”.

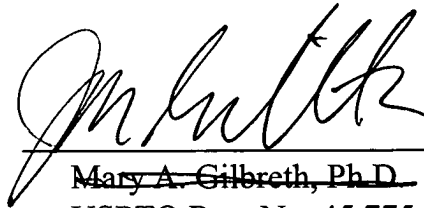
In response, independent claim 16 and dependent claims 19 and 20 are amended herein, and dependent claim 88 has been canceled. None of pending claims 16-20 contain the language and typographical error cited above and, as such, it is respectfully believed by the applicants that the rejection of claims 16-20 under 35 USC 112, second paragraph, has been overcome.

In view of the above Amendments and Remarks, prompt allowance of all pending claims is respectfully requested.

If it would be of assistance in resolving any issues in this application, the Examiner is kindly invited to contact applicants' agent Mary Gilbreth, or attorney Mark Gilbreth, at 713/667-1200.

Respectfully submitted,

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